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Comment on the ScHARR Assessment Report on Percutaneous Vertebroplasty and Percutaneous Balloon Kyphoplasty for the Treatment of Osteoporotic Vertebral Fractures

Dear Mr. Powell,

We would like to take the opportunity to comment on the Assessment Report issued the 8th August 2012 by the School of Health and Related Research (ScHARR), University of Sheffield, on the subject of percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures. We have participated in the Multiple Technology Assessment by submitting a Health Technology Assessment report on one of our key technologies in this area, the Vertebral Body Stenting System (VBS) for the management of spine fractures.

We were very pleased to see that the Asessment team has taken acount of the stentoplasty technology and is dedicating a specific chapter to it (p. 28-29). The features and benefits of the stenting technology are well described, especially the aim of overcoming the height loss occuring with the use of balloon kyphoplasty (p.28). We have been surprised, though, by one sentence mentioned at page 29:

"Anecdotally, stenting is associated with a greater risk of procedure-generated adjacent fractures, and some operators cement the adjacent vertebrae as a preventive measure."

We wonder where this statement is coming from. As manufacturer of VBS we are absolutely unaware of this. On the contrary, the currently available evidence that we summarized in our submission suggests that the rate of adjacent vertebral fracture lies somewhere around 9%, which

seems similar or even somewhat lower than the rates reported in the literature for vertebroplasty and balloon kyphoplasty. For example, Kasperk *et al.* reported 9.7% of adjacent level fractures after 3 years when using kyphoplasty and Mudano *et al.* reported 18.8% after 1 year for vertebroplasty and kyphoplasty[1] [2]. We would therefore strongly suggest that this sentence is removed from the report, particularly considering that there is no source given. We consider that statements that are "anecdotal" and without any supporting evidence should not be put forward in a Multiple Technology Assessment by NICE.

From a biomechanical perspective we believe that stentoplasty should not increase but reduce the risk of subsequent fractures, since the stent allows for a better kyphosis correction than both vertebroplasty and balloon kyphoplasty. A rebalancing of the spine shifts the center of gravity backwards which helps reducing the risk of further vertebral fractures. In our submission we have included five case series [3] [4] [5] [6] [7]. These studies account for a total of 209 patients with 148 being osteoporotic patients. The outcomes measured in these studies were pain, functional status, vertebral body height and angular deformity, progression of adjacent level vertebral fractures, cement leakage and stent opening. As we have specified in the submission the risk of adjacent and non-adjacent vertebral fractures has never been easy to estimate in an observational clinical study because it does not only rely on the augmentation technique itself, but can also be affected by external procedural parameters such as the number of vertebrae treated, the quantity of cement injected and the degree of cement leakage[8] [9] [10]. Therefore, the reasons for adjacent fracture are often not directly linked to the use of a specific implant such as a stent. For instance, we know from literature that more active patients have higher risks of additional fractures.

Muto *et al.*, did not record any new vertebral fractures in adjacent vertebrae at 12 month follow up. Although a new vertebral fracture was observed at a distant level, the study concluded that this fracture was probably caused by a natural evolution of the underlying osteoporotic disease. The study with the biggest number of patients treated with VBS (100 patients), Diel *et al.,* reported 10 new adjacent vertebral fractures occurring in 9 patients in the postoperative 3-months interval which corresponds to an adjacent fracture rate of 9% of patients. As mentioned above, this rate seems similar or even somewhat lower than the rates reported in the literature for vertebroplasty and balloon kyphoplasty.

The origin of the assertion about adjacent fractures in the Assessment Report could possibly come from a potential misunderstanding of the following sentence in the biomechanical study on VBS by Rotter et al.[11]:

"Biomechanical and clinical data show that hyperkyphotic posture leads to an increased fracture risk in the adjacent healthy vertebral levels. This appears to be particularly relevant in a growing group of patients in whom vertebral fractures of several levels have been observed within a short period of time, leading to a rapidly progressing kyphosis. This postural deterioration could eventually be stopped by restoring the height of fractured vertebrae and cementing several adjacent levels as a preventive measure (Heini et al 2004)".

The referred publication of Heini *et al*. in this quotation mentions indeed preventive cementing as a possible remedy to adjacent vertebral fractures. The authors argue that kyphotic postural deterioration can eventually be stopped by cementing several adjacent levels as a preventive measure, but they promote this for vertebroplasty, balloon kyphoplasty and stentoplasty alike, independently of the specific technology[12]. Preventive cementing does therefore not occur more often with Vertebral Body Stenting than with vertebroplasty or balloon kyphoplasty. We sincerely hope that this sentence will be removed in the final Multiple Technology Assessment Report.

Regarding the two double-blinded RCTs[13] [14] we were very pleased to see that Assessment Report acknowledges that the comparator (local injection of anesthesia) was not a real "sham" procedure but rather a pseudotreatment form which is rightly described by ScHARR as "operative placebo with local anaesthesia" (OPLA). It remains nevertheless doubtful whether such a treatment form can produce more than short term pain relief.

We would like to thank you for the opportunity to comment on the draft Assessment Report and are looking forward to the publication of the Final Report. If you require any further information, please feel free to contact us (email: iff.joel@synthes.com; phone: +41 61 965 65 48).

Yours sincerely,

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